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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/941,997	SHI ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 3-16* is/are pending in the application.

4a) Of the above claim(s) *4-8 and 10-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,9 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *2/12/02* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed July 25, 2005 has been entered. The examiner acknowledges the amendments to the specification. Claims 1, 3 and 9 have been amended. Claim 16 has been newly added. Claim 2 has been cancelled. Claims 4-8 and 10-15 have been withdrawn. Claims 1, 3, 9 and 16 are under consideration in this office action.

Withdrawal of Rejections

2. The enablement rejection of claims 2-4 and 8-9 under 35 U.S.C. 112, first paragraph has been withdrawn in view of applicants' amendments and arguments.

Response to Arguments

3. Applicant's arguments filed July 25, 2005 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The written description rejection of claims 1, 3 and 9 are rejected under 35 U.S.C. 112, first paragraph. The rejection was on the grounds that the written description in this case only sets forth the specific sequence identified by SEQ ID NO:2

to which the claimed polypeptide should correspond, therefore the written description is not commensurate in scope with the claims drawn to an isolated polypeptide consisting essentially of an N-terminal fragment of human cardiac troponin I having about 95 to about 115 amino acids or to an isolated polypeptide consisting essentially of a fragment of human cardiac troponin I wherein the N-terminus of the fragment is about amino 20 to about 30 and the C-terminus of the fragment is about amino acid 95 to about 115 of native human cardiac troponin I.

Applicants' assert that in light of the amendments, that the rejection should be withdrawn. However, the MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*,107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention

from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Furthermore, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.,* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). *Regents of the University of California v. Eli Lilly & Co.,* 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In *Gostelli*, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872 F.2d at 1012, 10 USPQ2d at 1618.

The generic claims are drawn to an isolated polypeptide consisting essentially of an N-terminal fragment of human cardiac troponin I having about 95 to about 115 amino acids or to an isolated polypeptide consisting essentially of a fragment of human cardiac troponin I wherein the N-terminus of the fragment is about amino 20 to about 30 and the C-terminus of the fragment is about amino acid 95 to about 115 of native human cardiac troponin I. However the specification fails to provide examples of what qualifying polypeptides of the claimed invention are. Moreover, SEQ ID NO:2 only has 99 amino acids, thus there is no teaching of polypeptides having about 115 amino acids.

As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim 1 is broad with respect all possible compounds encompassed by the claims. The possible structural variations are limitless. Moreover, the are no examples of polypeptides having about 115 amino acids. The specification and claims lack written description because there is no disclosure of a correlation between the function and structure of the compounds. Moreover, the specification lacks a sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of the claimed polypeptide. The specification is void of any molecules that qualify with regard to having 95 to about 115 amino acids or having a fragment of human cardiac troponin I wherein the N-terminus of the fragment is about amino 20 to about 30 and the C-terminus of the fragment is about amino acid 95 to about 115 of native human cardiac troponin I. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. *See In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ

369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Thus, in the absence of the identity of an isolated polypeptide consisting essentially of an N-terminal fragment of human cardiac troponin I having about 115 amino acids or to an isolated polypeptide consisting essentially of a fragment of human cardiac troponin I wherein the N-terminus of the fragment is about amino 20 to about 30 and the C-terminus of the fragment is about amino acid 95 to about 115 of native human cardiac troponin I, the instant specification fails to meet the written description requirements.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115). With the exception of specifically identified sequences, the skilled artisan cannot envision the detailed structure of an isolated polypeptide consisting essentially of an N-terminal fragment of human cardiac troponin I having about 95 to about 115 amino acids or to an isolated polypeptide consisting essentially of a fragment of human cardiac troponin I wherein the N-terminus of the fragment is about amino 20 to about 30 and the C-terminus of the fragment is about amino acid 95 to about 115 of native human cardiac troponin I; thus

conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules falling within the scope of the claimed genus.

Applicants' urge that the specification is an adequate and acceptable source for various functions of the claimed polypeptides. However the claims drawn to the polypeptides fail to recite any associated function. Without an associated function there is no limit on the polypeptides encompassed by applicants claims. It is noted that there is no requirement that the polypeptides have the ability to inhibit actin-myosin cross-bridges or regulate striated muscle contractions. Thus, the function of the instantly claimed polypeptides has not been defined and broadens the scope of the invention to encompass polypeptides not described by the instant specification.

Therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method for determining sequence identity, contrary to applicants' arguments. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of expression. The amino acid itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016. Currently the generic recitation of 90% identity is insufficient to support

the claim as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention. Therefore applicants' amendments and arguments are not persuasive and the rejection is maintained.

5. The rejection of claims 1 and 9 under 35 U.S.C. 112, second paragraph, is maintained for reasons already of record.

Applicants' assert that the reference sequence is that of human cardiac troponin I and is therefore clear. However the examiner urges that the claims are still indefinite. Hunkeler et al., (Circulation Research, 1991) teach that human cardiac troponin I has 210 amino acids. WO98/54218 teach that human cardiac troponin I has 209 amino acids. While WO97/19955 teaches that recombinant human cardiac troponin I has 226 amino acids. Therefore the claims are still unclear and indefinite because the claims fail to recite the reference sequence upon which the recited amino acids are based upon. There is no recitation of a reference sequence for troponin I for which the amino acids 20 to 30 to about 95 to about 115 is based upon. Without the reference sequence how will one know which 95 to 115 amino acids applicant is referring too. Therefore, the claims are indefinite and appropriate clarification is required to overcome the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. The rejection of claims 1, 3 and 9 under 35 U.S.C. 102(b) as being anticipated by Morjana et al., (WO97/19955) is maintained for reasons already of record. The rejection was on the grounds that Morjana et al., teach an isolated polypeptide consisting essentially of a N-terminal fragment of human cardiac troponin I fragment having about 95 to about 115 amino acids or to an isolated polypeptide consisting essentially of a fragment of human cardiac troponin I wherein the N-terminus of the fragment is about amino 20 to about 30 and the C-terminus of the fragment is about amino acid 95 to about 115 of native human cardiac troponin I.

Applicants' assert that the claimed fragments are not anticipated by or suggested by Morjana et al. It is first noted that "A consisting essentially of' claim occupies a middle ground between closed claims that are written in a consisting of' format and fully open claims that are drafted in a comprising' format." *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also *Atlas Powder v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569,

224 USPQ 409 (Fed. Cir. 1984); *In re Janakirama-Rao*, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); *Water Technologies Corp. vs. Calco, Ltd.,* 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). *In re Janakirama-Rao*, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (B (Bd. Pat. App. & Inter. 1989) ("Although consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps. . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by consisting essentially of' language.". See M.P.E.P. 2111.03[R-2] entitled Transitional Phrases. Therefore the claims are

interpreted to be inclusive or open-ended and do not exclude additional, unrecited elements or method steps. See, e.g., *Invitrogen Corp. v. Biocrest Mfg., L.P.,* 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003).

Moreover, it appears that applicants' claims recite open language since claim 3 also recites the term "having." The term "having" was interpreted as open terminology, allowing the inclusion of other components in addition to those recited); *Crystal Semiconductor Corp. v. TriTech Microelectronics Int 'l Inc.*, 246 F.3d 1336, 1348, 57 USPQ2d 1953, 1959 (Fed. Cir. 2001) (term "having" in transitional phrase "does not create a presumption that the body of the claim is open"); *Regents of the Univ. of Cal. v. Eli Lilly & Co.,* 119 F.3d 1559, 1573, 43 USPQ2d 1398, 1410 (Fed. Cir. 1997) (In the context of a cDNA having a sequence coding for human PI, the term "having" still permitted inclusion of other moieties.). Therefore the terms are open since there is no evidence to the contrary of record.

Morjana et al., teach a sequence with 99.7% sequence homology to SEQ ID NO: 2 of the instant application. The difference between Morjana et al., and the instant claims is that Morjana et al., teach additional amino acids, however since the claims are interpreted as allowing the inclusion of other amino acids in addition to those recited, Morjana et al., meet the limitation of the claims. Therefore, applicants' arguments are not persuasive and the rejection is maintained.

7. The rejection of claims 1 and 9 under 35 U.S.C. 102(b) as being anticipated by Moses et al., (WO 97/30085) is maintained for reasons already of record. The rejection

was on the grounds that Moses et al., teach an isolated polypeptide consisting essentially of a N-terminal fragment of human cardiac troponin I fragment having about 95 to about 115 amino acids or to an isolated polypeptide consisting essentially of a fragment of human cardiac troponin I wherein the N-terminus of the fragment is about amino 20 to about 30 and the C-terminus of the fragment is from about amino acid 95 to about 115 of native human cardiac troponin I.

Applicants' assert that Moses et al., is concerned with therapeutic activities associated with skeletal troponin I and only mentions cardiac troponin I in passing. However, the MPEP section 2123 teaches that patents are relevant as prior art for all they contain, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir.1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed."). If the prior art structure is capable of performing the intended use,

then it meets the claim. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967). In the instant case, Moses et al., teach that fragments can be at least 10 amino acids however the preferred embodiments are at least 50, 75, 100 or 120 amino acids long. And that the polypeptides can be cardiac troponin I isoforms from humans. Moreover, Moses et al., teach how to acquire the troponin fragments can be made by altering the troponin sequences with substitutions, addition or deletions that provide for functionally equivalent molecules, therefore the disclosure by Moses et al., meets the instantly claimed limitations since there are no structural differences. Therefore applicants' arguments are not persuasive and the rejection is maintained.

Applicants assert that Moses et al., do not teach or suggest from which part of the molecule to obtain such fragments and would not take guidance from the disclosure of Moses et al. However Moses et al., teach a prior art structure which meets the limitations of the claims, by teaching fragments having about 100 amino acids. The disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). Therefore applicants' arguments are not persuasive and the rejection is maintained.

8. The rejection of claims 1, 3 and 16 under 35 U.S.C. 102(e) as being anticipated by Potter et al., (WO97/39132) is maintained for reasons already of record. The rejection was on the grounds that Potter et al., teach an isolated polypeptide that corresponds to a human cardiac troponin I fragment comprised of about 95 to about 115 amino acids and SEQ ID NO:2.

Applicants' assert that because of the amendments, the fragments of Potter et al., do not read on the instant claims. However, Potter et al., teach human cardiac troponin I that has 100% sequence homology to SEQ ID NO: 2 of the instant application. Moreover the instant claims as discussed above recite transitional terms which are inclusive or open-ended and do not exclude additional, unrecited elements such as different amino acids. Thus the teaching of Potter et al., reads on the instant claims and the rejection is maintained since applicants' argument is not persuasive.

New Grounds of Objection and Rejection

Claim Objections

9. Claim 3 is objected to because of the following informalities: Claim 3 is dependent upon cancelled claim 2. Therefore appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in

the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claim is drawn to an isolated polypeptide consisting essentially of a fragment of human cardiac troponin I wherein the N-terminus of the fragment is about amino 20 to about 30 and the C-terminus of the fragment is about amino acid 95 to about 115 of native human cardiac troponin I. Neither the specification nor originally presented claims provides support for an isolated polypeptide consisting essentially of a fragment of human cardiac troponin I wherein the N-terminus of the fragment is about amino 20 to about 30 and the C-terminus of the fragment is about amino acid 95 to about 115 of native human cardiac troponin I.

Applicant did not point to support in the specification for an isolated polypeptide consisting essentially of a fragment of human cardiac troponin I wherein the N-terminus of the fragment is about amino 20 to about 30 and the C-terminus of the fragment is about amino acid 95 to about 115 of native human cardiac troponin I. Moreover, applicant failed to specifically point to the identity or provide structural characteristics of an isolated polypeptide consisting essentially of the C-terminus of the fragment is about amino acid 95 to about 115 of native human cardiac troponin I. Thus, there appears to be no teaching of that isolated polypeptide. Applicant has failed to pointed to pages within the instant specification or originally filed claims for support of the amendment; thus it appears that the entire specification appears to fail to recite support for the newly recited isolated polypeptide. Therefore, it appears that there is no support in the specification. Thus, applicants must specifically point to page and line number support

for the identity an isolated polypeptide consisting essentially of a fragment of human cardiac troponin I wherein the N-terminus of the fragment is about amino 20 to about 30 and the C-terminus of the fragment is about amino acid 95 to about 115 of native human cardiac troponin I as recited by the claim amendment. Therefore, the claim incorporates new matter and is accordingly rejected.

11. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "depicted" in the claim renders the claim unclear. It is suggested that applicant use terms such as "comprising", "consisting of" or "having". Therefore, the claims are rejected and appropriate clarification is required to overcome the rejection.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines

October 4, 2005

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